

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
27 July 2006 (27.07.2006)

PCT

(10) International Publication Number
WO 2006/078781 A1

(51) International Patent Classification:
A61F 5/00 (2006.01)

(21) International Application Number:
PCT/US2006/001842

(22) International Filing Date: 18 January 2006 (18.01.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/645,296 19 January 2005 (19.01.2005) US
60/662,570 17 March 2005 (17.03.2005) US
11/330,705 11 January 2006 (11.01.2006) US

(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier applications:
US Not furnished (CON)
Filed on 11 January 2006 (11.01.2006)
US 60/662,570 (CON)
Filed on 17 March 2005 (17.03.2005)
US 60/645,296 (CON)
Filed on 19 January 2005 (19.01.2005)

(71) Applicant (for all designated States except US): GI DYNAMICS, INC. [US/US]; 313 Pleasant Street, Watertown, Massachusetts 02472 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): LEVINE, Andy, H. [US/US]; 1105 Walnut Street, Newton, Massachusetts 02461 (US). RANDLE, Stuart, A. [US/US]; 359 Pope Road, Concord, Massachusetts 01742 (US). LAMPORT, Ronald, B. [US/US]; 66 Stonepost Road, Pelham, New Hampshire 03076 (US). MELANSON, David, A. [US/US]; 5 Schaefer Circle, Hudson, New Hampshire 03051 (US).

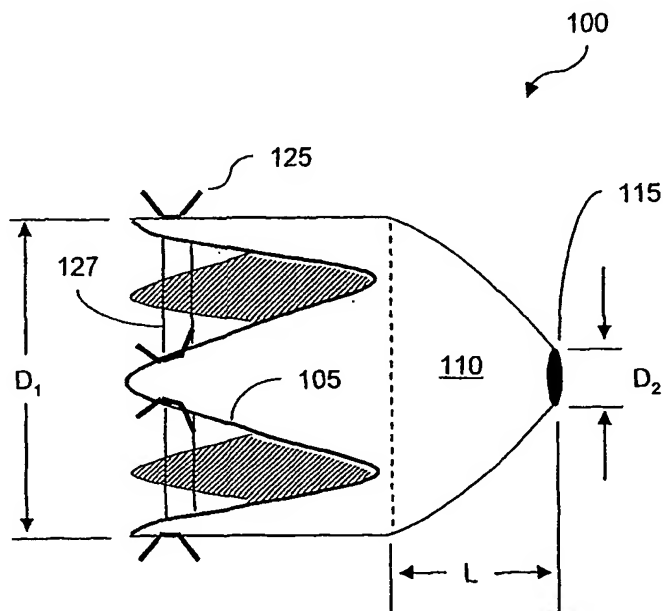
(74) Agents: SMITH, James, M. et al.; Hamilton, Brook, Smith & Reynolds, P.C., 530 Virginia Road, P.O. Box 9133, Concord, Massachusetts 01742-9133 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US (patent), UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),

[Continued on next page]

(54) Title: RESISTIVE ANTI-OBESITY DEVICES



(57) Abstract: A patient is provided with an increased sense of satiety by increasing resistance to the outflow of food from the stomach and through the intestines. Stomach emptying may be slowed with devices implantable within the gastrointestinal tract below the stomach. Implants are preferably removable and can include artificial strictures that may be adjustable to vary the rate of stomach emptying. Slowing gastric emptying may induce satiety for a longer period and may therefore reduce food consumption. Many of the embodiments include intestinal liners or sleeves, but they need not. The resistor concept may be applied to a simple anchor and resistor without a long liner.



European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

- 1 -

RESISTIVE ANTI-OBESITY DEVICES

RELATED APPLICATIONS

This application is a continuation of and claims priority to Attorney Docket No. 3588.1011-001 entitled "Resistive Anti-Obesity Devices" filed on January 11, 2006, which claims the benefit of U.S. Provisional Application No. 60/662,570, filed on March 17, 2005 and U.S. Provisional Application No. 60/645,296, filed on January 19, 2005. The entire teachings of the above applications are incorporated herein by reference.

BACKGROUND OF THE INVENTION

According to the Center for Disease Control (CDC), over sixty percent of the United States population is overweight, and almost twenty percent are obese. This translates into 38.8 million adults in the United States with a Body Mass Index (BMI) of 30 or above. The BMI is defined as a person's weight (in kilograms) divided by height (in meters), squared. To be considered clinically, morbidly obese, one must meet one of three criteria: BMI over 35, 100 pounds overweight, or 100% above ideal body weight. There is also a category for the super-obese for those weighing over 350 pounds.

Obesity is an overwhelming health problem. Because of the enormous strain associated with carrying this excess weight, organs are affected, as are the nervous and circulatory systems. In 2000, the National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK) estimated that there were 280,000 deaths directly related to obesity. The NIDDK further estimated that the direct cost of healthcare in the U.S. associated with obesity is \$51 billion. In addition, Americans spend \$33 billion per year on weight loss products. In spite of this economic cost and consumer commitment, the prevalence of obesity continues to rise at alarming rates. From 1991 to 2000, obesity in the U.S. grew by 61%. Not exclusively a U.S. problem, worldwide obesity ranges are also increasing dramatically.

One of the principle costs to the healthcare system stems from the co-morbidities associated with obesity. Type-2 diabetes has climbed to 7.3% of the population. Of those persons with Type-2 diabetes, almost half are clinically obese, and two thirds are approaching obese. Other co-morbidities include hypertension, coronary artery disease, hypercholesteremia, sleep apnea and pulmonary hypertension.

Although the physiology and psychology of obesity are complex, the medical consensus is that the cause is quite simple - an over intake of calories combined with a reduction in energy expenditures seen in modern society. While the treatment seems quite intuitive, the institution of a cure is a complex issue that has so far vexed the best efforts of medical science. Dieting is not an adequate long-term solution for most people. Once an individual has slipped past the BMI of 30, significant changes in lifestyle are the only solution.

There have been many attempts in the past to surgically modify patients' anatomies to attack the consumption problem by reducing the desire to eat. Stomach staplings, or gastroplasties, to reduce the volumetric size of the stomach, thereby achieving faster satiety, were performed in the 1980's and early 1990's. Although able to achieve early weight loss, sustained reduction was not obtained. The reasons are not all known, but are believed related to several factors. One of which is that the stomach stretches over time increasing volume while psychological drivers motivate patients to find creative approaches to literally eat around the smaller pouch.

Surgeries can generally be separated into restrictive procedures, malabsorptive procedures and combinations thereof. At least two surgical procedures that successfully produce long-term weight loss are the Roux-en-Y gastric bypass, and the biliopancreatic diversion with duodenal switch (BPD). Both procedures reduce the size of the stomach plus shorten the effective-length of intestine available for nutrient absorption. Reduction of the stomach size reduces stomach capacity and the ability of the patient to take in food. Bypassing the duodenum makes it more difficult to digest fats, high sugar and carbohydrate rich foods.

The Laparoscopic Adjustable Gastric Band is a device that is placed around the top of the stomach to create a restriction. This forces the patient to eat smaller meals as the food must pass from the small pouch into the rest of the stomach before he/she can eat again. This device however does require surgery for its placement and is difficult to remove.

These procedures carry a heavy toll. The morbidity rate for bariatric surgical procedures is alarmingly high with 11% requiring surgical intervention for correction. Early small bowel obstruction occurs at a rate of between 2-6% in these surgeries and mortality rates are reported to be approximately 0.5 -1.5%. While surgery is effective, the current invasive procedures are not acceptable with these complication rates. Laparoscopic techniques applied to these surgeries result in fewer surgical complications but continue to expose these very ill patients to high operative risk in addition to requiring an enormous level of skill by the surgeon. Devices to reduce absorption in the small intestines have been proposed (see U.S. Patent Number 5,820,584 (Crabb), U.S. Patent Number 5,306,300 (Berry) and U.S. Patent Number 4,315,509 (Smit)). However, these devices have not been successfully implemented. Restrictive devices include Laparoscopic Adjustable Gastric Banding (LABG) (see for example U.S. Patent Number 5,226,429 (Kuzmak)) and gastric balloons (see for example U.S. Patent Number 4,823,808 (Clegg et al.) and U.S. Patent Number 6,755,869 (Geitz)).

SUMMARY OF THE INVENTION

The present invention relates to methods, devices and systems that provide an increased sense of satiety to a person by increasing the resistance to the outflow of food from the stomach. Gastric emptying can be slowed using devices that slow the passage of chyme through the intestines. Slowing gastric emptying may induce satiety for a longer period and may therefore reduce food consumption. Although many of these concepts include intestinal liners, they need not. The resistor concept may be applied to a simple anchor and resistor without a long liner.

Restrictive devices have been previously described but most commonly are described to reside within the stomach. Anchoring devices in the stomach is difficult as the stomach is a particularly active region of the anatomy tending to tear

out devices implanted therein. The devices described herein are more typically anchored in the intestines.

Devices which include liners can be implanted within the intestine to prevent the contact of partially-digested food (*i.e.*, chyme) with the intestine thereby
5 reducing one or more of hormone triggers, digestion and absorption of nutrients. By adding a resistive feature to these devices passage of chyme through the device can be slowed. By reducing the flow below a rate at which chyme flows in an unrestricted intestine, the chyme can build up along a proximal end of the device. The chyme build-up slows the gastric emptying process, as there will be less volume available within the intestine to accommodate additional chyme from the stomach, or the pressure required to pass the chyme from the stomach to the intestine is higher than normal.

It is believed that slowing emptying of the stomach may ultimately reduce the amount of food a patient consumes. Alternatively or in addition, an intestinal implant device creating a resistance within the intestine requires the bowel to exert more energy to propel the chyme than would otherwise be necessary without the resistance. Such a restriction can slow gastric emptying, cause higher energy expenditure, and lead to weight loss.

Methods are provided for inducing weight loss within a patient by treating a region of the intestine below the pyloric sphincter and slowing gastric emptying responsive to the treated region, resulting in a prolonged feeling of satiety by the patient. The treatment can include implanting at least a portion of a device below the pyloric sphincter. Preferably, the implanted device reduces the flow of chyme into the proximal intestine. For example, the device provides an artificial stricture through which the chyme passes. The artificial stricture can include a diaphragm narrowing the intestinal lumen. The diaphragm can include a membrane defining a reduced aperture. Alternatively or in addition, the artificial stricture can include a liner defining a central lumen through which chyme passes, the artificial stricture being coupled to the liner.

In some embodiments, the artificial stricture is adjustable. For example, the stricture can be formed using an adjustable member coupled to adjust the diameter of the interior lumen of a liner. The adjustable member can be combined with a

securing feature adapted for adjustably securing the adjustable member in place once a desired restriction is achieved. In other embodiments, the adjustable member includes a balloon that can be adjusted by inflation and deflation.

In other embodiments, the restrictive element is elastomeric and passively
5 controls the outlet pressure of the stomach by varying in diameter depending on the inlet pressure.

In other embodiments, the implanted device includes a dampening liner adapted to reduce peristaltic efficiency. The dampening liner can be a semi-rigid liner. In yet another embodiment, the implanted device occupies a non-negligible volume within the intestine, thereby reducing the available intestinal volume and limiting the amount of chyme that can be accommodated.

Alternatively or in addition, the present invention relates to a gastrointestinal implant including a resistive feature adapted to be secured within the intestine and distal to the pyloric sphincter. When implanted, the resistive feature impedes gastric emptying. An anchor can be coupled to the resistive feature for attaching the resistive feature to the gastrointestinal tract. In some embodiments, the resistive feature includes a sleeve or liner defining a central lumen through which chyme can pass. The liner itself can define a central lumen having a constricted region of a reduced diameter.

In another embodiment the gastrointestinal implant includes a resistive coating provided on an interior surface of the liner. For example, the resistive coating can include artificial cilia aligned to impede the passage of chyme. In yet other embodiments, the resistive feature includes a bent wire, such as a contorted wire formed from a resilient wire, such as Nitinol wire.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention.

FIG. 1A is a schematic diagram illustrating a side view of the embodiment of the invention including an artificial stricture;

FIG. 1B is a schematic diagram of an end view of the embodiment of FIG. 1A;

5 FIG. 2 is a graph illustrating the pressure drop of an exemplary fluid through an orifice of varying size;

FIG. 3 is a side view of an embodiment of the invention including a liner having one or more restrictive members;

FIGS. 4A-4D are end views showing alternative types of restrictive members used in the embodiment of the invention shown in FIG. 3;

FIG. 5 is a schematic diagram illustrating an embodiment of the invention including a liner having a narrowed region;

FIG. 6 is a schematic diagram illustrating an alternative embodiment of the invention including a tapered segment and a narrowed region;

FIG. 7 is a schematic diagram illustrating an embodiment of the invention including a tapered liner;

FIG. 8A is a schematic diagram illustrating an embodiment of a tapered anchor;

FIG. 8B is a schematic diagram illustrating an exemplary mandrel used to form the tapered anchor of FIG. 8A;

FIGS. 9A and 9C are schematic diagrams illustrating side views of an embodiment of the invention including a drawstring restrictor shown in the open and partially-closed positions, respectively;

FIGS. 9B and 9D are schematic diagrams illustrating end views of the embodiment of the invention shown in FIGS. 9A and 9C, respectively in the open and partially-closed positions;

FIG. 10A is a schematic diagram illustrating a side view of an embodiment of a ball-and-cleat locking mechanism for locking the drawstring of FIGS. 9A-9D;

FIG. 10B is a schematic diagram illustrating a side view of an embodiment of a hook-and-eyelet locking mechanism for locking the drawstring of FIGS. 9A-9D;

FIG. 10C is a schematic diagram illustrating a side view of an embodiment of a crimp-type locking mechanism for locking the drawstring of FIGS. 9A-9D;

FIG. 10D is a schematic diagram illustrating a cross-sectional side view of an embodiment of a friction locking mechanism for locking the drawstring of FIGS. 9A-9D;

FIG. 10E is a schematic diagram illustrating an axial cross section of the embodiment shown in FIG. 10D;

FIG. 11A is a schematic diagram illustrating a side view of an embodiment of the invention including an inflatable restrictive member;

FIG. 11B is a schematic diagram illustrating an end view of the inflatable restrictive member shown in FIG. 11A;

FIG. 12 is a partially-cut-away schematic diagram illustrating an embodiment of the invention providing a thick-walled liner; and

FIG. 13 is a partially-cut-away schematic diagram illustrating an embodiment of the invention providing an internal resistive surface;

FIG. 14A is a schematic diagram illustrating a side view of an embodiment of the invention including a solid mass within the intestine;

FIG. 14B is a schematic diagram illustrating an end view of the embodiment including a solid-mass shown in FIG. 14A;

FIG. 15 is a schematic diagram illustrating a cross-sectional view of an embodiment of the invention using a filter; and

FIG. 16A is a schematic diagram illustrating the artificial structure of FIG. 1A implanted within the proximal duodenum; and

FIG. 16B is a schematic diagram illustrating a repositioning device engaging the artificial structure of FIG. 1A.

DETAILED DESCRIPTION OF THE INVENTION

A description of preferred embodiments of the invention follows.

This general concept relates to providing an increased sense of satiety by slowing gastric emptying by providing resistance to the outflow of food from the stomach and through the intestines. An increased sense of satiety is obtained by slowing emptying of an animal's stomach. Gastric emptying can be slowed by providing resistance to the outflow of food, or chyme, from the stomach. In general,

an animal perceives a sensation of satiety when the stomach fills. It is believed that by slowing gastric emptying into the duodenum, an animal can maintain a feeling of satiety for a longer period of time. Consequently, an animal no longer feeling hungry will tend to eat less.

- 5 There are several approaches that can be used to increase resistance to flow of the chyme. For example, a device having features adapted to resist the flow of chyme can be implanted within the gastrointestinal tract distal to the stomach. At least one approach is simply placing a sleeve or liner within the intestine. The mere presence of the liner can add some resistance to the flow of chyme therethrough.

Alternatively or in addition, an implant can include at least one resistive feature, such as a reduced-diameter aperture, or stricture, that artificially narrows a region of the gastrointestinal tract. A resistive implant is preferably placed at a predetermined location within the body and adapted to remain there throughout a course of treatment. To maintain the implant in place, at least a portion of the device is secured to the surrounding anatomy. Securing of an implant can be accomplished using an anchor coupled to the device. Anchoring within the gastrointestinal tract, however, poses numerous challenges due at least in part to the physiology of the anatomical region, its high degree of motility, and pressures resulting from digestive forces.

One region of the gastrointestinal tract that is particularly well suited for anchoring the resistive implant is the proximal duodenum. Compared to the stomach, the pylorus, and even distal regions of the small intestine, the proximal duodenum is relatively immotile. Additionally, the proximal duodenum defines a slightly enlarged cavity just distal to the pyloric sphincter referred to as the duodenal bulb. An anchor of the type shown in FIG. 1A that expands to conform to the lumen is particularly well suited for positioning within the bulbous duodenum. The shape of the cavity and its relatively low motility will enhance performance of the anchoring device.

An exemplary artificial stricture 100 adapted for gastrointestinal applications is illustrated in FIG. 1. The device 100 includes an anchoring element 105 coupled to an artificial stricture. The artificial stricture retards the flow of chyme therethrough. The anchor 105 is adapted to anchor the device 100 within the

gastrointestinal tract. When placed at or below the pylorus, the stricture operates to slow gastric emptying. The anchor is adapted to hold the device securely in place under gastrointestinal forces and pressures.

5 The anchor can be a radial spring defining an opening therethrough for the passage of chyme and adapted to engage the surrounding tissue of the hollow organ within which it is implanted. Thus, the anchor 105 can provide an interference fit to the surrounding tissue. In some embodiments, the perimeter of the anchor is in sealable communication with the surrounding tissue of the lumen to prevent leakage of chyme and fluids beyond the artificial stricture.

The artificial stricture can be formed from a blocking material 110 coupled to the anchor 105, the blocking material defining an aperture 115 therein. For example, the blocking material can include the same materials described in more detail below in reference to intestinal liners. The blocking material is dimensioned to at least cover the cross-sectional area of the lumen within which it is implanted. For an implant adapted for use in the proximal duodenum of an adult male, the diameter of the impermeable material would be at least about 25 millimeters.

The stricture is created by forming an aperture 115 having a reduced cross-sectional area, or diameter within the blocking material 110. The aperture can be formed, for example, by simply cutting or punching a hole of the appropriate dimensions into the blocking material 110. For example, the hole can be less than about 10 millimeters in diameter for the exemplary 25 millimeter implant. In some embodiments, the aperture is about 5 millimeters in diameter or less. It is unlikely, however, that an orifice of less than about 2 millimeters would be used in a human application as food particle passing through the pylorus are typically about 1-2 millimeters or less in size.

Fluid mechanics can be used to determine the size orifice needed to provide a restriction within the duodenum. For example, the Bernoulli equation can be applied to the flow of a Newtonian fluid through an orifice as provided in equation 1. In this equation, ΔP represents the pressure drop across the orifice, ρ corresponds to the fluid density, Q corresponds to the volume flow (determined as the product of the fluid velocity and the flow area), D is the diameter of the unobstructed opening (e.g., about 25 mm in the example of FIG. 2), and d is the diameter of the orifice in

millimeters. In the example of FIG. 2, the diameter of the orifice is varied between about 2 and 10 mm.

$$\Delta P = (8\rho Q^2)/(\pi^2 D^4) * [(D/d)^4 - 1] \quad (1)$$

5

An exemplary graph of the pressure drop through an orifice of varying size is provided in FIG. 2. The graph was determined by applying equation 1 using an assumed velocity of about 2 cm/sec, which corresponds to the mean flow rate of chyme through the intestines. Considering peristaltic pressures on the order of 20-40 inches of water (an exemplary range of pressures corresponding to an adult human) the orifice size should be less than about 5 mm in diameter to provide flow resistance. More preferably, the orifice size is less than 5 mm. For example, an orifice of about 3 mm provides increased flow resistance under nominal anticipated peristaltic pressures.

In some embodiments, the aperture is adjustable. For example, an aperture can be increased by stretching it until the blocking material defining the aperture plastically deforms to a new, larger diameter. Stretching can be accomplished using a balloon inserted into the aperture, the balloon being inflated after insertion. The pressure of the inflated balloon will stretch a suitable blocking material to a larger size. When the balloon is removed, the material will retain the enlarged aperture. In other embodiments, the blocking material is elastomeric such that the aperture is permitted to temporarily expand above certain pressures to prevent blockage of the aperture for food particles larger than the minimum dimension the aperture returning to its reduced diameter thereafter.

Referring again to Fig. 1, the anchor 105 generally defines a central lumen through which chyme flows. The anchor can include a stent, such as the stents described in U.S. Patent Application Serial Number 10/339,786 filed on January 9, 2003, incorporated herein by reference in its entirety. Alternatively or in addition, the anchor can include a radial spring, such as the wave anchor illustrated and described in more detail in U.S. Patent Application Serial Number 10/858,851 filed on June 1, 2004 and incorporated herein by reference in its entirety.

The anchor 100 can attach to the intestine using a frictional or interference fit. Thus, the anchor can have a relaxed diameter that is greater than the maximum anticipated diameter of the intestine, such that the anchor will provide an outward force against the adjacent anatomy acting to keep the anchor in place. Alternatively
5 or in addition, the anchor 105 can include one or more external barbs 125 further securing the implant device in the presence of peristalsis. Preferably, the barbs 125 are sized and positioned to engage muscular tissue. Exemplary barbs are described in more detail in U.S. Patent Application Serial Number 10/339,486, and U.S. Patent Application Serial Number 10/858,852 filed on June 1, 2004 incorporated herein by reference in its entirety.

The anchor 100 can also include one or more repositioning features. As shown the device includes a drawstring 127 at its proximal end. The drawstring 127 is threaded through the open end of the anchor 100 such that it can be grasped and used to facilitate repositioning of the anchor 100 within the body or removal of the anchor 100 from the body. Removal methods and devices using a drawstring are described in U.S. Application Attorney Docket No. 3588.1008-001, entitled "Removal and Repositioning Device" filed on December 22, 2005 and incorporated herein by reference in its entirety.

In some embodiments, an anchor is attached to a material similar to the blocking material. For example, the anchor can be encapsulated between overlapping layers of a tubular segment of blocking material. The blocking material 110 defining the aperture 115 can then be formed in the same blocking material that is attached to the anchor 105. Alternatively, a different blocking material can be used.

The blocking material 110 can first be formed into a suitable pattern, such as the circle shown and then attached to the anchor and/or to material covering the anchor 105. When the anchor 105 is also attached to the blocking material, the different segments of blocking material can be sealably attached together using any suitable means. For example, the blocking material 110 can be attached to the anchor covering by suturing. Alternatively or in addition, the blocking material 110 can be attached to the anchor covering by a chemical fastener, such as an adhesive, and/or by thermal bonding. Formed in this manner, the attached blocking material

110 may extend for some distance L from the distal end of the anchor 105 when in the presence of a proximal pressure (e.g., the material bulges out in an elongated or domed fashion). In some embodiments, the blocking material 110 is attached in a relatively taught manner, similar to the skin of a drum to limit any axial extent L of the blocking material 110 beyond the distal end of the anchor 105.

In some embodiments, the resistive implant includes a liner. As shown in FIG. 3, an implant device 200 includes an elongated liner 210 adapted for placement within a hollow organ, such as the intestine. In some embodiments, the implant 200 includes an anchor 205 coupled to the liner 210, with the anchor 205 adapted to secure at least a portion of the liner 210 within the lumen of the intestine. For example, a hollow anchor similar to those anchors described above can be attached to the proximal end of the liner 210 to secure the proximal end of the liner 210 to the surrounding tissue of the intestine. Once implanted, the liner 210 is extended distally from the anchor along the intestine.

Preferably, any of the implantable devices described herein can be configured to be removable. Thus, any permanence of a resistive device only applies during the period in which the device is implanted within the patient. Thus, a resistive device can be removed should the need arise. Alternatively or in addition, a different or even the same resistive device can be re-implanted within the same patient.

The liner 210 can be formed from a thin yet durable biocompatible material and is generally unsupported and tending to collapse upon itself when empty. For example, the liner 210 can be formed from a fluoropolymer, such as expanded polytetrafluoroethylene (ePTFE). In some embodiments, the liner material is formed using a combination of different materials, such as ePTFE with a different fluoropolymer such as fluorinated ethylene propylene (FEP). The combination of ePTFE and FEP provides a low coefficient of friction, while also being substantially non-permeable. Alternatively or in addition, the liner is formed using polyolefin (e.g., LPDE, HPDE, polypropylene) films. Gastrointestinal liners are described in more detail in U.S. Patent Application Serial Number 10/339,486 filed on January 9, 2003, incorporated herein by reference in its entirety.

The liner 210 can have a diameter corresponding to the nominal expanded diameter of the lumen within which it is implanted. Current liners being used in porcine testing include diameters of about 25 millimeters, believed to be close to the diameter of the bowel. A liner having a similar diameter is also believed to be
5 suitable for use within the proximal portion of the small intestine of an adult human. The length of the liner can vary from centimeters to a meter or more depending upon the particular application.

The liner 210 provides the added feature of preventing contact between the intestinal walls and any chyme contained therein. The liner can also delay the mixing of chyme with digestive enzymes secreted within the intestine.

In some embodiments, the liner implant includes an eversion-resistance zone adapted to reduce the likelihood of eversion of the liner in a proximal direction (*i.e.*, toward the stomach). Without precautions, a negative pressures or reverse peristalsis within the intestine (*e.g.*, when vomiting) will tend to push the liner back through the anchor. The eversion resistance zone can be provided by reinforcing a region of the liner, just distal to the anchor. Liners having eversion resistant features are described in U.S. Patent Application No. 11/147984, filed on June 8, 2005 claiming priority to Provisional Application No. 60/645,296 filed on January 19, 2005 incorporated herein by reference in their entireties.

The liner 210 can include one or more restrictive elements 215a, 215b (generally 215) positioned therein to partially block the intestinal lumen thereby impeding the flow of chyme and subsequently delaying emptying of the stomach. The restrictive elements 215 can include diaphragms that provide a partial blockage within the liner. For example, the diaphragm can be formed from an impermeable membrane defining an aperture or orifice that is smaller than the diameter of the liner 210. The diaphragms can have different orientations and configurations adapted to produce a desirable resistance to the flow of chyme within the liner 210.

The anchored liner 210 provides a framework for positioning and securing the diaphragms 215. As illustrated, a first diaphragm 215a is attached to the liner at a first distance L_1 measured distally from the proximal end of the liner. A second diaphragm 215b can optionally be attached to the liner 210 at a second distance L_2 measured distally from the first diaphragm 215a. The distal end of the liner 210 can

terminate at the location of the last diaphragm 215 or optionally may extend further as illustrated.

Exemplary diaphragms 215 are described below and can be attached to the liner using any suitable method of attachment. For example, the diaphragms 215
5 can be attached using chemical fastening means, such as adhesives or thermal bonding. Alternatively or in addition, the diaphragms 215 can be attached using mechanical fastening means, such as sutures, staples, and clips.

The diaphragm 215 can take on any conceivable shape. Exemplary diaphragms are shown in FIGS. 4A through 4D. A diaphragm 300 defining a single aperture or orifice 305 is shown in FIG. 4A. The orifice 305 is defined within a diaphragm providing a closed surface 300. The orifice 305 provides a reduced-diameter stricture.

An alternative embodiment is a partial-block diaphragm 310 is shown in FIG. 4B. The partial-block diaphragm 310 is shaped and positioned to block a portion of the intestinal lumen. As shown, the partial-block diaphragm 310 can include a planar surface bounded between a chord 312 and the perimeter of the adjacent liner 314. Selection of the chord controls the surface area of the bounded diaphragm 310 and subsequently controls the percent blockage provided. For example, selection of a chord 312 corresponding to a diameter of the circular arc will result in a 50% blockage. More generally, the shape of the partial-block diaphragm 310 can take on other forms and need not be limited to the exemplary shape described herein.

In another embodiment shown in FIG. 4C, the diaphragm 320 includes more than one smaller orifices 325. The number and size of the orifices 325 can be used to control the percent blockage of the lumen resulting in resistance to the flow of chyme. Additionally, the diameter of the orifices 325 themselves can be used to provide further resistance by limiting the size of solids allowed to pass. For example, multiple circular orifices 325 can be distributed in a regular or irregular pattern across the surface of the diaphragm 320.

In some embodiments, the diameter of the diaphragm is about 25 mm, corresponding to the internal diameter of the liner 210, with each orifice 325 having a respective smaller diameter (e.g., about 3 millimeters or less). Alternatively or in

addition, the size of the aperture can be increased by removing one or more portions of the diaphragm between groups of orifices 325. Such alterations can be accomplished prior to implantation of the device, or *in situ* using an endoscope. The material can be removed or the aperture otherwise enlarged by selectively cutting
5 the material between different apertures. In some embodiments, perforations 326 are provided between different orifices 325 and along the diaphragm itself to facilitate alterations.

In yet other embodiments, the diaphragm 330 includes a screen or sieve as illustrated in FIG. 4D. A screen or sieve 335 can be coupled to a frame 330 to facilitate attachment to the diaphragm 330 to the liner 210

Alternatively or in addition, an artificial stricture can be created within the liner itself. An exemplary liner-based stricture device 400 is shown in FIG. 5. The device 400 includes an elongated liner 410 having an internal diameter and defining a reduced diameter over at least a portion of the liner length. In some embodiments, the device 400 includes an anchor 405 coupled to the proximal end of the elongated liner 410 to retain the device within the gastrointestinal tract when implanted therein as described above. The liner 410 contains an axial region 412 having a reduced diameter to provide a permanent restrictor 415. For instance, the liner 410 could be reduced in diameter forming the hourglass configuration shown. Thus, the elongated liner's diameter measured along its axis transitions from a first diameter D_1 (e.g., 25 millimeters), at a proximal end and for a predetermined length L along the liner, to a lesser diameter D_2 (e.g., about 3 to 10 millimeters). The reduced diameter persists at least briefly, and then may or may not transition back again to a larger diameter (e.g., back to D_1).

In some embodiments the lesser diameter (e.g., D_2) persists for only a short distance resulting in the hourglass configuration; whereas, in other embodiments the reduced diameter may extend for a predetermined length along the axis. The resulting reduced diameter provides a permanent stricture, or narrowed orifice, tending to slow gastric emptying by reducing the rate at which chyme flows through the orifice and consequently through any portion of the intestine proximal to the orifice.

In another embodiment, not shown, substantially the entire length of the liner can be sized having a diameter smaller than would otherwise be provided by the intestine alone. For example, a liner defining a central lumen with a diameter less than 25 millimeters (*e.g.*, between about 5 and 20 millimeters) would also impede the flow of chyme by increasing its flow resistance.

In an alternative embodiment shown in FIG. 6, an implantable device 500 includes a restrictor formed by a liner 510 coupled at its proximal end to an anchor 505 adapted to anchor the liner with the gastrointestinal tract. In particular, the device 500 includes an aperture 515 having a reduced diameter D_2 , similar to that describe above in relation to FIG. 5. Additionally, however, the device 500 includes a tapered liner segment 520 between the anchor and the aperture 515. The tapered segment 520 transitions a first diameter D_1 to a lesser diameter by "necking down" a proximal portion of the device. The tapered segment 520 can be accomplished in a reinforced region of the liner just distal to the anchor 505 (*e.g.*, the eversion-resistant feature). Such a restrictor provides a permanent orifice, of a diameter less than the natural lumen, thereby slowing gastric emptying. It is believed that the tapered region 520 will reduce the loss of water from the chyme suspension that might otherwise occur in a more abrupt transition.

Alternatively or in addition, the length of the liner can slow gastric emptying. Some test observations indicate that animals having longer liner implants (*e.g.*, 4 ft, or about 1.2 meters) appear to eat less, or at least less quickly, than do animals with similar, but shorter liners (*e.g.*, 2 ft, or about 0.6 meters). At least one reason that the length of the liner matters is that the longer the liner, the slower the propagation of chyme through it. An animal may have a greater sense of fullness as the chyme winds through the intestines more slowly. Also, the intestines may need to work harder to pass the chyme. Thus, the liner length can affect energy expenditure directly.

Abrupt restrictions, such as those provided by the hourglass taper (FIG. 5) and the diaphragm (FIGS. 3 and 4) are focal restrictions in that they transition from a larger diameter to a smaller diameter over a relatively short distance. One disadvantage of such focal restrictions is that they may lead to an abrupt and unwanted separation of water from the chyme suspension at the orifice, making the

chyme thicker and more difficult to pass. One means of avoiding this unwanted removal of water is to provide a liner that is tapered gradually over its length.

As shown in FIG. 7, an implantable device 600 includes a liner 610 coupled at its proximal end to an anchor 605, which is adapted to anchor the device 600 within the gastrointestinal tract. The liner provides a first diameter D_1 at its proximal end closer to the stomach and a second diameter D_2 that is less than the first diameter at its distal end, further from the stomach. Thus, the diameter of the liner varies or tapers between the first and second diameters along a length L . The particular profile of the taper is selectable and can be chosen, for example, at the time the liner is formed. Thus, the diameter of the liner can change along its length in a linear fashion, as shown. Alternatively or in addition, the diameter can change along the length of the liner according to one or more other mathematical functions including polynomial, exponential, and/or logarithmic functions. Preferably, the chyme would remain well hydrated through the liner until the distal end where a larger restriction would lie.

Illustrated in FIG. 8A is a schematic diagram of an embodiment of the invention including a tapered anchor 705. The anchor 705 can be formed providing a proximal opening 710 having a first diameter D_1 and a distal opening 715 having a second diameter D_2 that is less than the first. The anchor 705 can be formed from rigid or semi-rigid material. For example, the anchor can be formed from an alloy, such as stainless steel or Nitinol. In some embodiments, at least the distal region of the anchor is resilient, temporarily expanding to pass material sized larger than the second diameter therethrough, then returning to its reduced diameter. For example, the distal opening 715 can flex outward, temporarily opening to a larger diameter D_2' when subjected to an expanding force 716 due to elevated internal pressure above about 75 inH₂O. This would permit the anchor to open if it became obstructed with a large food particle and relieve the obstruction as the stomach forces chyme through at elevated pressure. Tapered anchors 705 can be combined with any of the other features described herein including a liner and one or more diaphragms. When combined with a liner, sufficient excess liner material is provided to allow expansion of the anchor's distal end.

Wire anchors, such as the wave-type anchors described above can be formed by forming a wire about a mandrel. An exemplary mandrel 750 that can be used to form a tapered anchor is shown in FIG. 8B. The mandrel 750 is shaped according to a desired taper profile having a first diameter D_1 at its proximal end 755 and a tapered region leading to a reduced diameter D_2 at its distal end 760. The mandrel 750 may contain other features to facilitate forming the anchor thereon. For example, the mandrel 750 shown provides a number of posts 765 about which a wire is bent to form a tapered anchor.

In some embodiments, the artificial stricture provides an adjustable orifice. For example, the adjustable orifice can be provided within a gastrointestinal liner. Thus, the diameter of the orifice can be adjusted to selectably increase and/or decrease its diameter. Varying the diameter of the orifice similarly affects the resistance offered by the device to the flow of chyme therethrough and can be advantageous for tailoring performance of the device during a particular course of treatment. For example, if a patient outfitted with an adjustable device is not losing weight sufficiently, the diameter of the orifice can be altered to vary the performance (*i.e.*, the orifice can be narrowed to provide more restriction, ideally leading to greater weight loss). Preferably, adjustments to the orifice can be accomplished remotely or using an endoscopic procedure and without the need for surgery. Alternatively or in addition, adjustment can be accomplished through a remote, subcutaneous route.

An exemplary embodiment of an artificial stricture having an adjustable orifice is illustrated in FIGS. 9A through 9D. An intestinal implant 800 includes an anchor 805 coupled to a length of liner 810. At least a portion of the liner is altered to form an adjustable orifice or restriction. As shown, the liner 810 can be altered using a drawstring 820. For example, the implant 800 includes a collapsible lumen and a drawstring. The collapsible lumen is operable by adjusting the drawstring 820 to selectively change the size of a constriction within the lumen. Thus, the drawstring can be used to alter the size of the orifice between an unconstrained diameter D_1 (FIG. 9A) and a reduced diameter D_2 (FIG. 9C). In some embodiments, the drawstring 820 is provided at a distal end of a relatively short gastrointestinal liner 810, as shown. Alternatively, the liner 810 may extend for a predetermined

length and the drawstring 820 positioned at any preferred location along the length of the liner 810.

The drawstring 820 can be sewn into the liner 810 in a purse string fashion, as shown. That is, the drawstring can be laced through holes or eyelets 825 formed in the liner material and extending about the perimeter of the liner 810 (FIG. 9B).
5 Alternatively or in addition, the drawstring can be inserted into a hem or a casing, provided within the liner 810 (not shown). Usually, when using a hem or a casing at least one access port will be necessary through which the drawstring can be grasped for adjustment.

In some embodiments, the drawstring includes at least one feature adapted for grasping. For example, the drawstring can include at least one loop 822 that may extend within the interior lumen of the liner. The loop 822 can be grasped by a device and manipulated to alter the diameter of the liner. As shown in FIG. 9D, pulling the loop 822 results in a reduction of the diameter of the liner 810.

In yet other embodiments, the drawstring 820 can be used to adjust the diameter of the anchor 805 itself. For example, the drawstring 820 can be woven through the distal end portion of an anchor 805 (not shown), such that an adjustment of the drawstring 820 changes the diameter of the distal end of the anchor 805.

Once implanted, the drawstring 820 can be accessed remotely (*e.g.*, endoscopically). An instrument, such as a hook, or pinchers can be used to grasp an exposed portion of the drawstring. Once grasped, the drawstring 820 can be adjusted to create a smaller or larger opening. For example, the drawstring 820 can be pulled away from a wall of the liner 810 (*e.g.*, radially inward), in a proximal or distal direction along the length of the liner 810 (*e.g.*, axially), or in a combination of both radial and axial directions.

The drawstring 820, once adjusted, can include a feature, such as a locking means, to retain the drawstring 820 in the adjusted position. It should be noted that locking the drawstring holds it in place to prohibit any further unintentional adjustment (*e.g.*, expansion) of the orifice. Preferably, the locking means is reversible such that it can be locked, unlocked, and then locked again for re-adjustment. For example the drawstring can include a mechanical clip, or more simply a knot, suitably placed to limit further adjustment. In some embodiments a

knot can be provided in the drawstring to prohibit expansion of the device beyond a maximum diameter as set by placement of the knot.

Shown in FIG. 10A is a cross-sectional view of an embodiment of a liner having a ball-and-cleat locking means adapted to lock a drawstring 920, once
5 adjusted. A portion of the drawstring 920 is wrapped around a segment of the liner 910, such that the drawstring 920 can be used to narrow the interior of the liner 910. For example, one end of the drawstring 921 can be secured with respect to the liner 910. The free end of the drawstring 920 can then be wrapped about the exterior of the liner 910, forming a loop thereabout. The free end can be further threaded through an opening 922 into the interior of the liner 910. By adjusting, or pulling the free end of the drawstring 920 with respect to the secured end 921, the diameter of the loop is reduced, thereby reducing the interior diameter of the liner.

A number of balls 930, or knots, are provided along a portion of the drawstring 920 (e.g., a suture). As the drawstring 920 is adjusted, a portion of the drawstring 920 containing the ball 930 is coupled to a cleat 935 to restrict further adjustment of the drawstring. The cleat 935 can be coupled to the liner 910 or more preferably to a portion of the anchor 905.

In another embodiment (not shown), at least a proximal portion of the drawstring can be replaced by a sturdy tape with an integrated gear rack, or notched belt. A ratchet including an opening can be attached to the liner or anchor. The ratchet includes a pawl that selectively engages teeth along the belt as a free end of the belt is threaded through the ratchet. Thus, similar to a cable tie-wrap device, the drawstring can be adjusted in one direction by simply pulling the free end of the belt. Adjustment in an opposite direction is generally prohibited by the pawl.

FIG. 10B is a cross-sectional view of an alternative embodiment of an adjustable implant device 940 using a hook-and-eyelet locking means for locking a drawstring 920'. Thus, one or more hooks 950 are provided along a portion of the liner. A loop 955 or eyelets formed in the drawstring 920' are adapted to engage at least one of the hooks 950. A portion of the drawstring 920' is wrapped around a segment of the liner 910, such that the drawstring 920' can be adjusted to narrow the interior of the liner 910. The hooks 950 are configured to selectably engage a loop or eyelets 955 to secure the drawstring 920' once adjusted. For example, a linear

array of hooks 945 can be attached to the anchor 905 and/or to the liner 910. The drawstring 920' is adjusted, as described above, and a portion of the drawstring 920' is in position to engage a selected one of the array of hooks 945 corresponding to a preferred diameter of the liner 910.

- 5 Alternatively or in addition, a crimp-type locking means can be used to crimp a portion of the drawstring thereby restricting further adjustment. One embodiment of a crimp-type locking means is shown in FIG. 10C. Thus, a graspable feature 965 of a drawstring 960 is pulled through one or more crimpable elements 970. When the drawstring 960 is positioned to produce a desired aperture, at least one of the crimpable elements 970 is crimped about the drawstring 960. If further adjustment is necessary, the crimpable element 970 securing the drawstring 960 can be breached to free the drawstring 960. After further adjustment, the drawstring 960 can be secured again by crimping another one of the crimpable elements 970 to again secure the drawstring 960.

Yet another embodiment of a friction-type locking means is shown in FIG. 10D. A portion of the drawstring 960 is drawn through a resilient channel 980 that is biased in a "pinched" or closed position. Thus, referring to the cross-sectional diagram of FIG. 10E, the walls of the resilient channel 980 pinch a portion of the drawstring 960 without application of an external force, thereby maintaining the drawstring 960 in fixed position. Subsequent adjustment of the drawstring is possible by applying an external force that flexes the compliant channel (e.g., forces 981', 981'' directed along the arrows of FIG. 10E) thereby counteracting its biasing force. When flexed in this manner, the resilient channel 980 conforms to an open configuration as indicated in phantom, thereby releasing its grip on the drawstring 960. Thus, the resilient channel 980 is opened (*i.e.*, the pinch is removed), which allows the portion of the drawstring contained therein to be further adjusted. Once readjustment is completed, the external force is removed from the resilient channel 980 allowing it to revert to its biased configuration to pinch the drawstring, once again holding it fixed. In some embodiments, the resilient channel 980 includes internal features, such as teeth 985, adapted to enhance the securing force provided to the entrapped portion of the drawstring 960.

In some embodiments, as shown in FIGS. 11A and 11B, an implant 1000 includes an adjustable orifice provided by an inflatable device, such as a balloon. For example, the interior aperture 1015 of a toroidal balloon 1012 defines a central orifice having a diameter D_2 . The adjustable orifice (e.g., balloon 1012) can be
5 coupled to either an anchor 1005 or a liner 1010 coupled at its proximal end to the anchor 1005. As illustrated, a balloon 1012 is attached to a proximal portion of the liner 1010. In some embodiments in which the balloon 1012 is attached to the anchor 1005, without a liner 1010. The balloon 1012 can be attached to either the liner 1010 or the anchor 1005 using any suitable means of attachment including mechanical fasteners, such as sutures or clips, or chemical fasteners, such as adhesives or bonding.

To adjust the internal diameter of the toroidal balloon 1012, once implanted, an endoscope (not shown) can be inserted into the patient and directed to an area near the balloon 1012. A needle can then be passed through the endoscope to the balloon 1012. The balloon 1012 can include a septum through which the needle can access the balloon 1012. A fluid, preferably such as water, or even a gas, can be injected into or removed from the balloon 1012 selectively inflate or deflate the size of the balloon 1012, thereby adjusting the size of the orifice 1015 between different-sized apertures 1017', 1017'' as shown in FIG 11B.

In some balloon embodiments, the implant 1000 includes a small inflation/deflation tube 1025 coupled between the balloon 1012 and a remote location 1030. The tube 1025 can be used to inflate and/or deflate the balloon 1012 by allowing a fluid or gas to be transferred into or out of the balloon 1012 from the remote location 1030. In some embodiments, the small tube 1025 passes from the balloon 1012 proximally into the stomach, and through a wall of the stomach into a subcutaneous reservoir. Alternatively, the small tube 1025 passes from the balloon 1012 to an injection port 1020. Preferably, the injection port 1020 is located just below the skin 1021. Thus, a needle can be used to pierce the skin 1021 for accessing the injection port 1020. Once accessed, the needle is again used to transfer a fluid or gas between to or from the balloon 1012, thereby adjusting the size of the balloon 1012. In other embodiments, one end of the tube 1025 exits the

patient. Again, fluid could be injected into or removed from the balloon through this tube 1025 to adjust the size of the opening.

In addition to simply providing a narrower channel through which chyme will flow, the liner can reduce the efficiency of natural peristalsis. Peristalsis refers to the forces exerted by the intestine to mix and pass chyme distally through the intestine. In the presence of a liner, peristaltic forces provided by the intestine must operate upon the chyme through the liner material. Preferably, the liner is adapted to channel most if not all of the chyme through its central lumen.

In some embodiments, the efficiency of peristalsis can be reduced by using a dampening liner. A dampening liner includes preferred material properties adapted to absorb and/or resist at least some of the peristaltic force provided by the intestine. Thus, liners that are thicker and/or more rigid will tend to dampen the peristaltic forces more so than thinner liners formed from the same material.

Such a dampening liner can be configured for implantation within the digestive tract to reduce efficiency of peristalsis. A partially-cut-away of an embodiment of a dampening liner 1100 is shown in FIG. 12. A thick-walled liner 1110 is coupled at its proximal end to an anchor 1105 adapted for implantation within the gastrointestinal tract. The stiffer the material of the liner 1110, the less effective peristalsis will function since the forces that the intestine exerts to pass chyme F_1 must work through the liner material 1110. Thus the resulting forces acting upon chyme within the liner 1110 are represented by a second force F_2 that is less than F_1 due at least in part to the damping features of the liner 1110.

In some embodiments, it may be desirable to have a relatively flexible liner near the bile and pancreatic ducts so as not to block the ampulla of Vater, but a stiffer material more distal, to increase resistance to flow. Thus, the properties of the liner material can be varied along the liner. For example, the same material can be provided with various thicknesses to control variations in the damping performance of the liner along its axis. Alternatively or in addition, different materials can be combined to provide the desired damping values. Configurations can include overlapping portions of the same and/or different materials and/or adjacent regions formed from different materials.

Alternatively or in addition, the device can include an interior surface adapted to impede the flow of chyme. For example, as shown in the partially-cut-away schematic diagram of FIG. 13, the a textured liner device 1200 includes a liner 1210 coupled at its proximal end to an anchor 1205. The interior
5 surface of the liner 1210 wall includes surface features designed to interfere with the flow of chyme, thus acting to retard the flow against natural peristaltic forces. The surface features can include multiple artificial cilia 1215. Preferably, the artificial cilia 1215 are oriented in a proximal direction to maximize their effectiveness. The artificial cilia 1215 can be created by brushing or abrading the interior surface of the liner 1210 in a direction against the flow of chyme. This can raise a nap in the surface of the material biased to the direction of the abrasion.

Gastric emptying can also be slowed by implanting a mass having a non-negligible volume within the intestine. A blocking mass takes up room within the intestine causing a restriction of sorts within the intestine at least along the length of the mass. Consequently, progression of chyme through the intestine is slowed. The mass provides a smaller volume within the intestine within which to hold chyme as well as a smaller lumen cross-sectional area for the chyme to pass.

In an exemplary embodiment, an implantable mass 1300 shown FIG. 14A can be implanted within the duodenum to slow the progression of chyme within a portion of the intestinal lumen. In some embodiments, the mass 1300 can be implanted at least partially in other parts of the intestine that may be distal to the duodenum. The mass 1310 can include a solid material, such as a rod. The rod can be solid, braided, or have any other suitable linear construct capable of being attached to the anchoring means 1305 and extended into the intestine.

The elongated, or rod-type blocking mass 1310 is implanted axially along the duodenum, such that the available area of a cross section of the intestine is reduced by the cross-sectional area of the blocking mass, as shown in FIG. 14B. The implanted mass 1310 can also slow gastric emptying by simply occupying a portion of the available volume within the intestinal lumen. Thus, both the length and diameter of the blocking mass can be adjusted to occupy a selectable volume.

Still further, the implanted mass 1300 can reduce the efficiency of peristalsis by absorbing or blocking at least a portion of the peristaltic force applied to chyme

in the vicinity of the implanted mass 1300. Thus, the density and/or compliance of the blocking mass 1300 can also be selected to suitably reduce peristaltic efficiency.

As illustrated, the blocking mass 1310 can be anchored in the intestine using a gastrointestinal anchor 1305, such as any of the anchoring devices described
5 above. For example an anchor 1305 is attached to the proximal end of the blocking mass 1310 using any suitable attaching means. Alternatively or in addition, the blocking mass 1310 can be attached to the intestine without an attached anchor 1305. For example, the blocking mass 1310 can be attached using mechanical fasteners, such as barbs, clips, sutures, staples, etc. As suturing to an intestine can be difficult, the sutures can extend from the implant within the intestinal lumen, through the intestine wall, and to another portion of the anatomy located outside of the intestine. Preferably, the mechanical fasteners couple to muscular tissue to securely anchor the device 1300. Alternatively or in addition, the blocking mass 1310 can be attached using other attaching means, such as chemical fasteners (*e.g.*, surgical adhesives).

In yet another embodiment, an aperture can be formed from one or more contorted elongated elements, such as bent wires. An exemplary embodiment is shown in the axial cross section of FIG. 15. One or more elongated members 1425 (*i.e.*, wires) can be twisted in an irregular, convoluted manner to produce resistance to the passage of chyme. The resistance is due at least in part to reduced apertures or screen formed by overlapping portions of the convoluted wire 1425. In some embodiments the wire is a metal wire, such as a metal alloy. In a preferred embodiment, the wire is a Nickel-Titanium alloy referred to as a Nitinol. The wire can be anchored within the intestine using any suitable anchoring means 1430, such as mechanical fasteners, barbs, sutures, etc. In some embodiments, the implanted wire provides sufficient force for an interference fit keeping it in place. Anchoring can be enhanced with any of the above anchoring means by locating the anchor 1420 in a proximal portion of the duodenum 1400, just distal to the pyloric sphincter 1420 and proximal to the ampulla of vater 1422, referred to as the duodenal bulb 1420.

A cross section of a proximal duodenum 1400 is illustrated in FIG. 16A including an artificial stricture 100 (FIG. 1A) implanted therein. The stricture is positioned distal to the pylorus 1410 and proximal to the ampulla of vater 1422, in

the duodenal bulb 1420. The stricture 100 includes barbs 125 that are sized to engage muscular tissue of the intestine. The radial expansive force of the anchor maintains the proximal end of the stricture 100 sealably engaged with the interior walls of the duodenal bulb 1420. The radial force is also sufficient to keep the barbs
5 125 firmly implanted within the surrounding tissue. Chyme emptying into the duodenum 1400 through the pylorus 1420 encounters the artificial stricture 100. The reduced aperture of the stricture decreases the rate at which chyme passes into the distal duodenum 1400. As chyme continues to empty from the stomach, the chyme builds up along a proximal side of the stricture 100. Thus, the stomach empties at a slower rate than would otherwise occur without the stricture due to its reduced aperture of the stricture 100. Exemplary fluid flow rates can be 2 cm/sec through a 25 mm diameter opening.

The stricture material 100 may be constructed of a compliant or non-compliant polymer. If non-compliant, such as .0005" thick ePTFE and FEP, then the hole size remains fixed and also can be dilated with a balloon as it will plastically deform. If compliant, such as with .015" thick, 40-60A durometer silicone, the hole may enlarge in response to elevated pressures that result when the hole gets obstructed by large food particles.

Another means to provide a self-clearing restriction is if a compliant band is placed around the liner or outlet. One such concept would be made if the drawstring 820 of FIG 9C were replaced with a loop about 3 mm in diameter formed using a thin elastomeric band. If the orifice becomes obstructed, stomach pressure would rise and the elastomeric band may increase in diameter and relieve the obstruction.

As described above, the artificial stricture 100 can include a drawstring 125 to assist in the repositioning or removal of the device 100. As shown in FIG. 16B, a repositioning device 1500 having a grasping element 1505 can be inserted into the body to grasp a portion of the device 100. For example, the repositioning device 1500 can be inserted endoscopically through the stomach and at least partially through the pylorus 1420 to a region near the proximal end of the implanted device 100. The grasping element 1505 can then be manipulated to engage the drawstring 125 of the device 100 for repositioning or removal.

- 27 -

While this invention has been particularly shown and described with references to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the scope of the invention encompassed by the appended claims. It
5 should also be appreciated that the various features of the embodiments that have been described may be combined in various ways to produce numerous additional embodiments. Moreover, while various materials, dimensions, shapes, implantation locations, types of anchors, etc. have been described for use with the disclosed embodiments, others besides those disclosed may be utilized without extending the scope of the invention, including implantation locations in or above the pylorus.

CLAIMS

What is claimed is:

1. A method for treating obesity comprising:
5 implanting a device within a gastrointestinal tract of an animal distal to the pylorus; and
 with the implanted device, resisting the outflow of food from the stomach.
2. The method of claim 1, wherein the step of implanting comprises a non-surgical procedure.
3. The method of claim 2, wherein the non-surgical procedure comprises an endoscopic procedure.
4. The method of claim 1, wherein the implantable device has an artificial stricture.
5. The method of claim 4, further comprising the step of adjusting the artificial stricture to vary the resistance provided to the outflow of food from the stomach.
6. The method of claim 1, wherein the implantable device has a textured surface exposed to resist the natural flow of chyme.
7. The method of claim 1, wherein the step of increasing resistance to the outflow of food from the stomach comprises aligning an implantable mass within the duodenum, the mass occupying a non-negligible volume.
8. The method of claim 1, wherein the step of increasing resistance to the outflow of food from the stomach comprises inhibiting the effectiveness of peristaltic forces.

9. The method of claim 1, wherein the implanting step comprises removably anchoring the device within the gastrointestinal tract.
- 5 10. The method of claim 1, further comprising the step of removing the device from the gastrointestinal tract.
11. A gastrointestinal implant comprising:
 - an anchor adapted for implantation within a gastrointestinal tract of an animal at a position distal to the animal's pylorus; and
 - a resistive element in communication with the anchor, the anchor removably securing the resistive element in position and the resistive element retarding the outflow of food from the stomach.
12. The gastrointestinal implant of claim 11, wherein the resistive element comprises an artificial stricture.
13. The gastrointestinal implant of claim 12, wherein the artificial stricture is adjustable to selectively vary resistance provided thereby to the outflow of food from the stomach.
14. The gastrointestinal implant of claim 12, wherein the artificial stricture comprises a diaphragm.
15. The gastrointestinal implant of claim 12, wherein the artificial stricture comprises a balloon, the balloon being adjustable to selectively vary resistance provided thereby to the outflow of food from the stomach.
16. The gastrointestinal implant of claim 12, wherein the artificial stricture comprises an elongated liner defining a lumen through which chyme passes, the liner having a non-uniform diameter along its axis.

17. The gastrointestinal implant of claim 15, wherein the liner includes an axial length having a reduced diameter that is bounded on either end by an adjacent portion of liner having a greater diameter.
- 5 18. The gastrointestinal implant of claim 15, wherein the liner includes a gradual taper over a non-negligible length from a first diameter to a lesser diameter.
19. The gastrointestinal implant of claim 11, wherein the resistive element reduces effectiveness of peristaltic forces, thereby retarding the outflow of food from the stomach.
20. The gastrointestinal implant of claim 11, wherein the resistive element comprises an elongated liner formed from a substantially non-permeable material and defining a lumen through which chyme passes, the liner material reducing effectiveness of peristaltic forces.
21. The gastrointestinal implant of claim 11, the resistive element comprises a liner defining a lumen through which chyme passes, the liner having a textured surface adapted to retard the flow of chyme contained therein.
22. The gastrointestinal implant of claim 11, wherein the anchor comprises a radial spring adapted to sealably engage tissue of the gastrointestinal tract.
23. The gastrointestinal implant of claim 11, wherein the anchor further comprises at least one barb adapted for insertion into muscular tissue of the gastrointestinal tract.
24. A gastrointestinal implant for treating obesity comprising:
 - means for increasing within the intestine resistance to the outflow of food from the stomach; and
 - means for anchoring within a gastrointestinal tract of an animal and distal to the pyloric sphincter the means for increasing resistance.

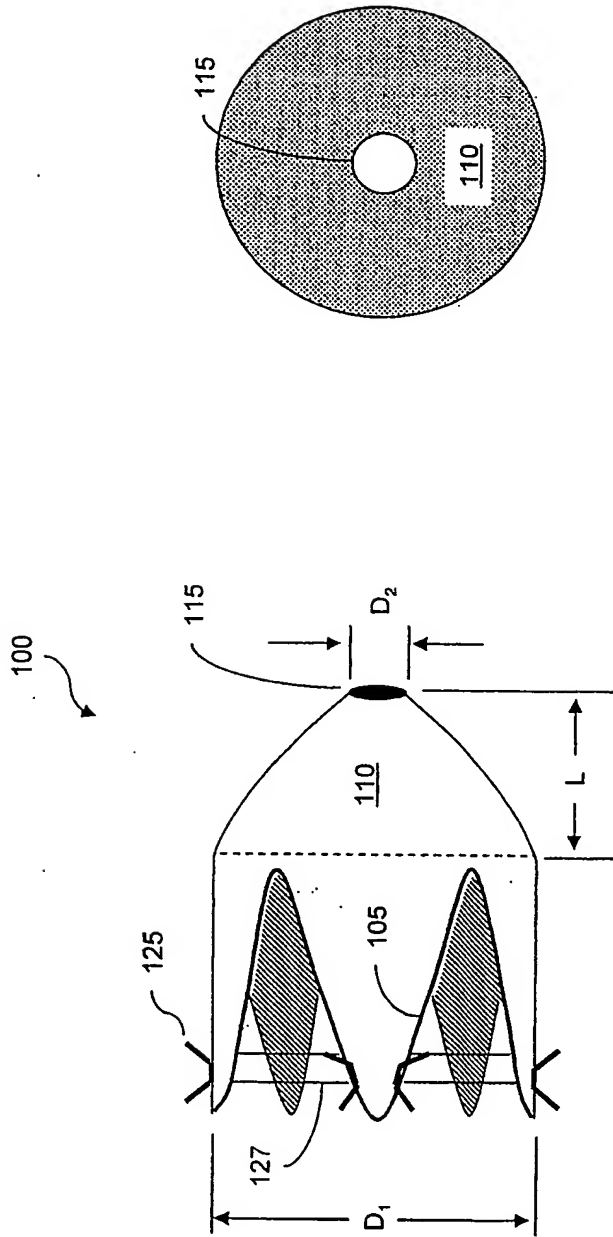


FIGURE 1A

FIGURE 1B

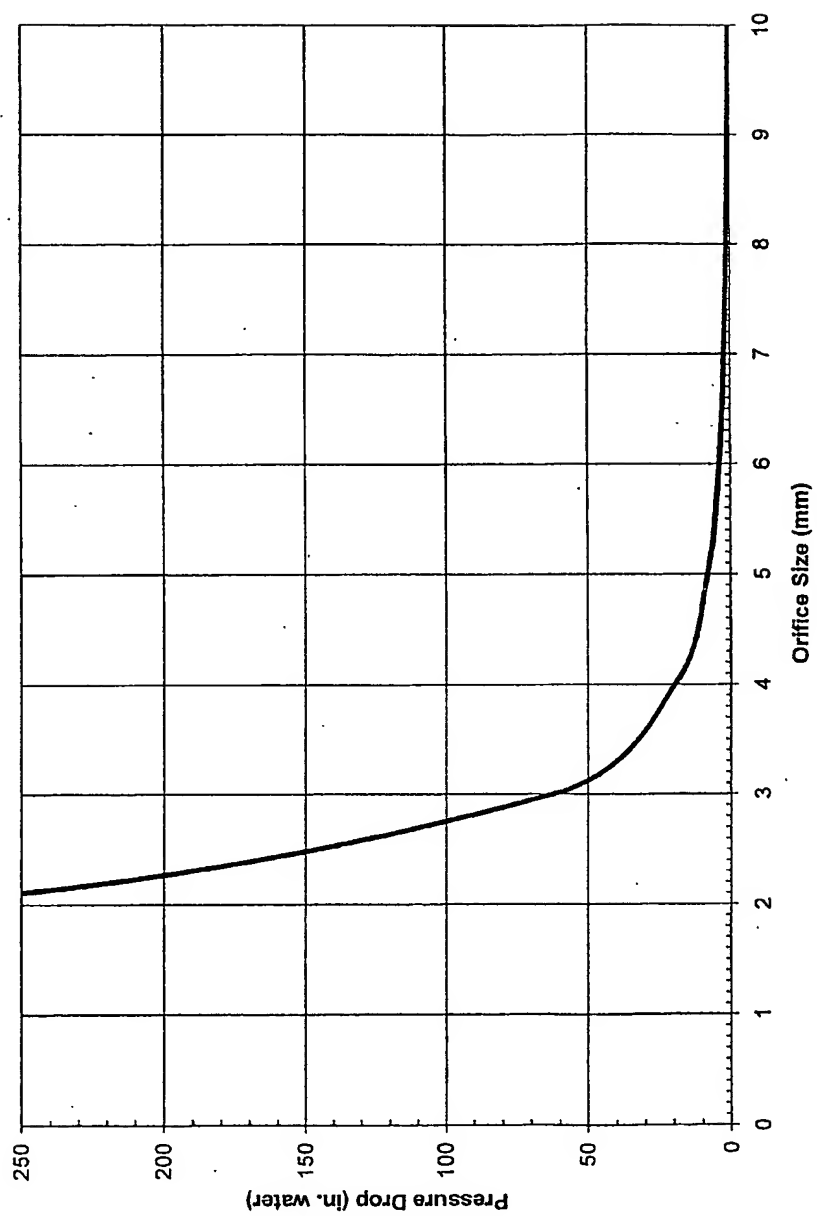


FIGURE 2

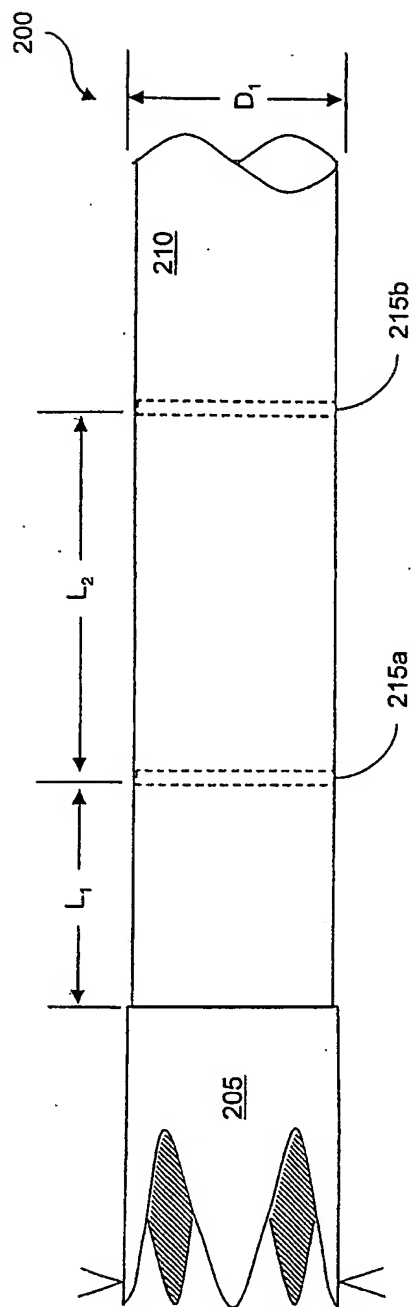


FIGURE 3

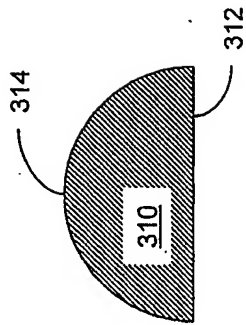


FIGURE 4B

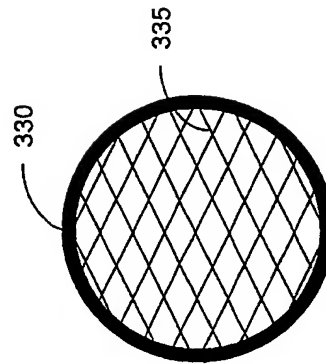


FIGURE 4D

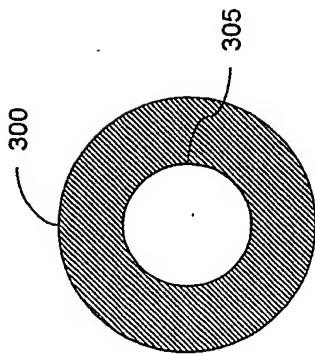


FIGURE 4A

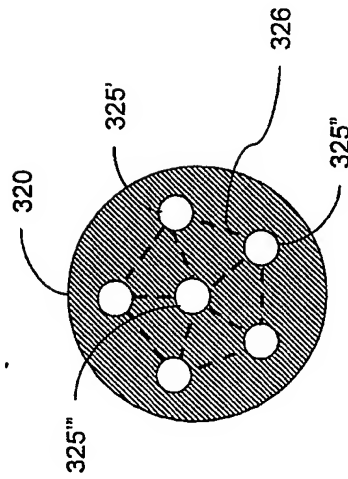


FIGURE 4C

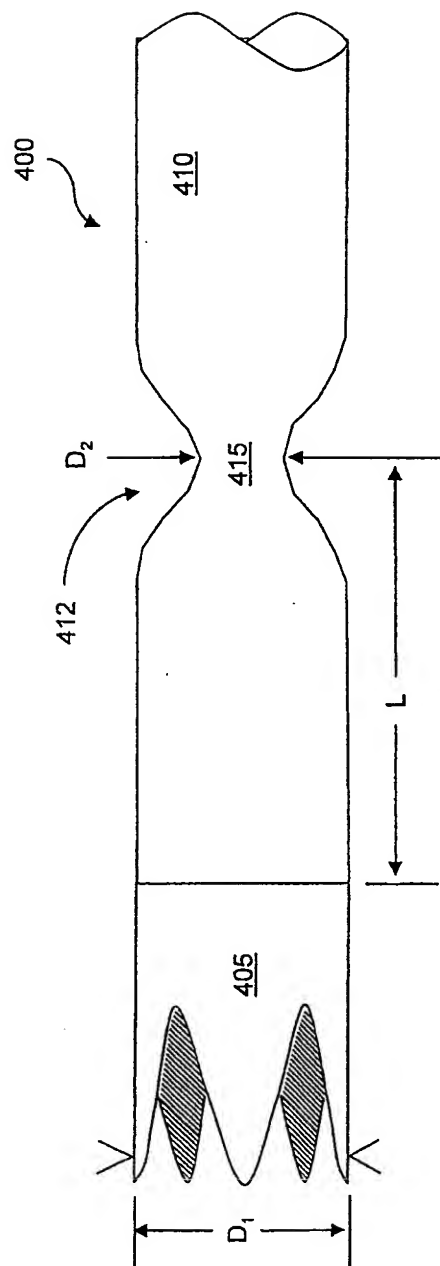


FIGURE 5

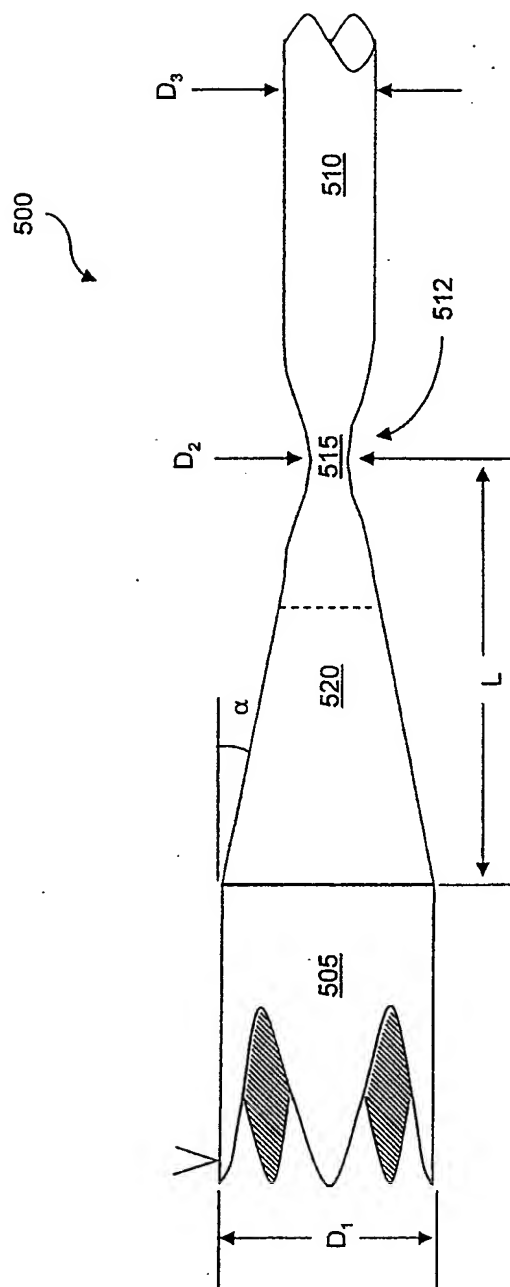


FIGURE 6

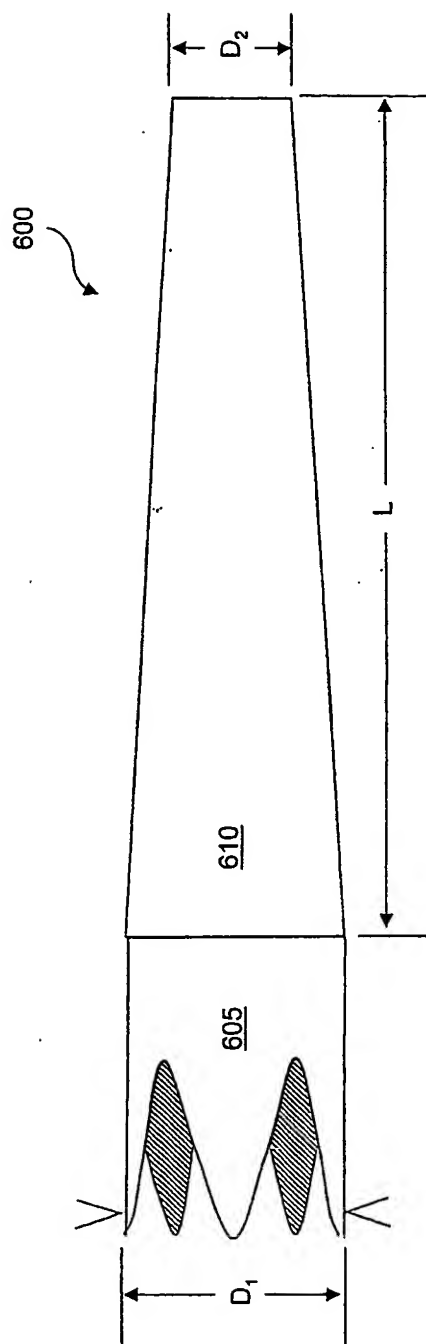


FIGURE 7

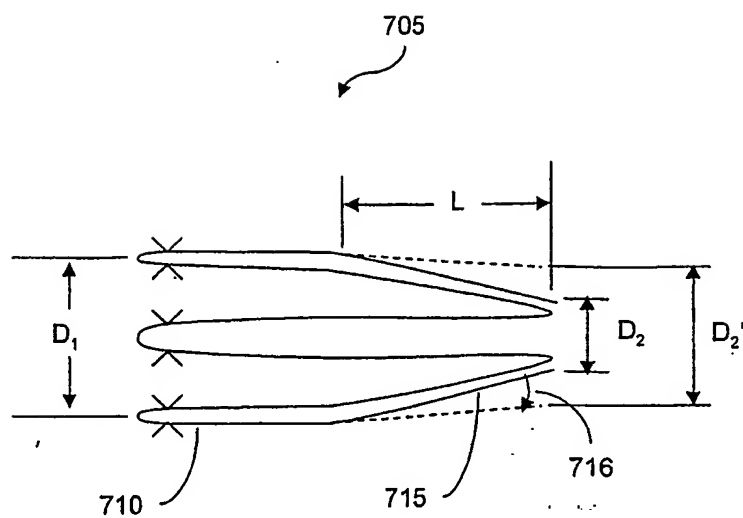


FIGURE 8A

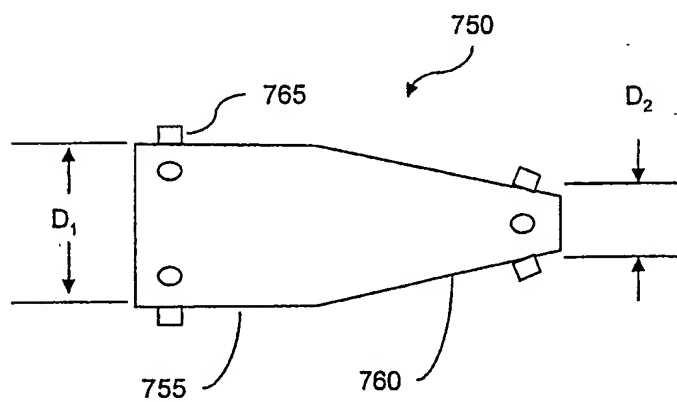


FIGURE 8B

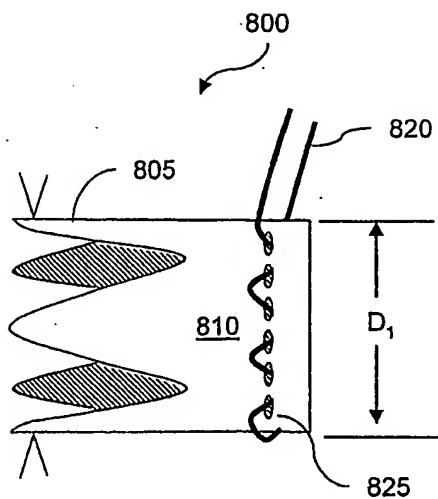


FIGURE 9A

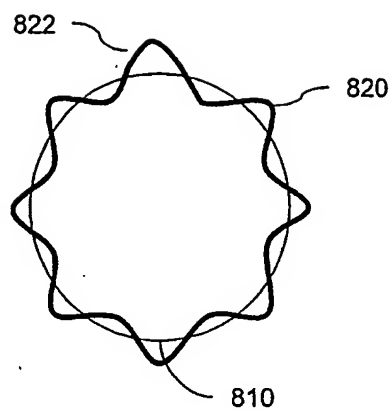


FIGURE 9B

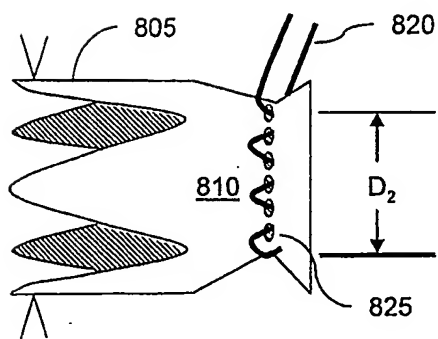


FIGURE 9C

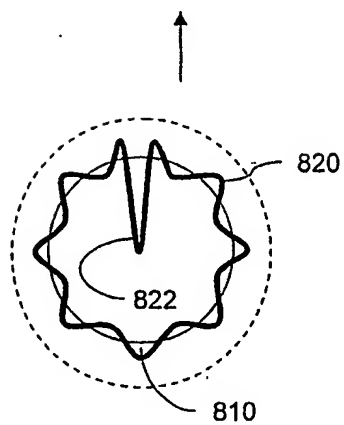


FIGURE 9D

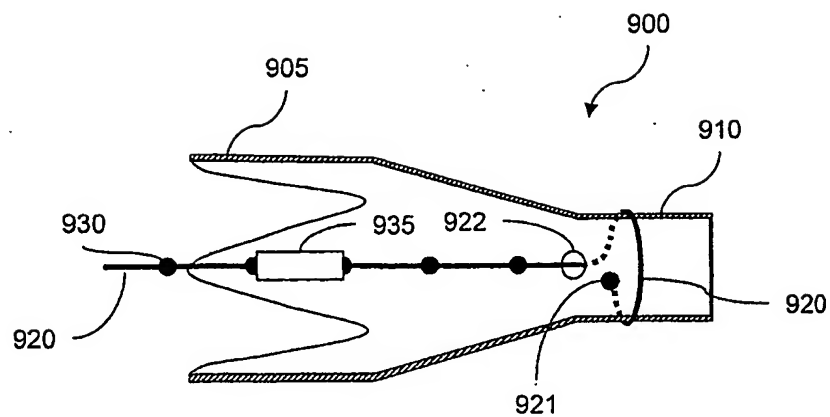


FIGURE 10A

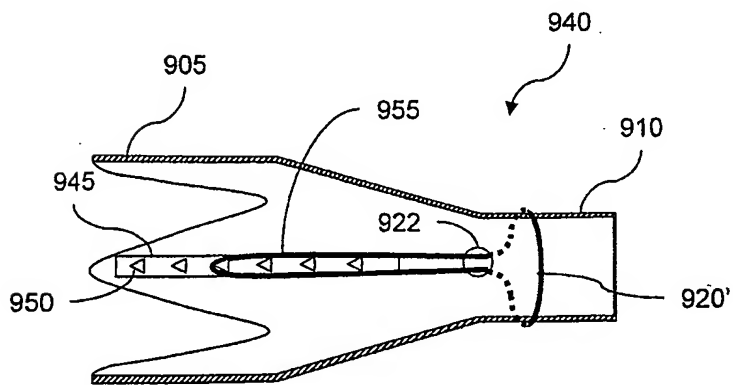


FIGURE 10B

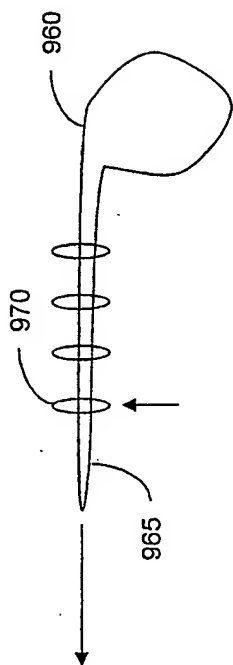


FIGURE 10C

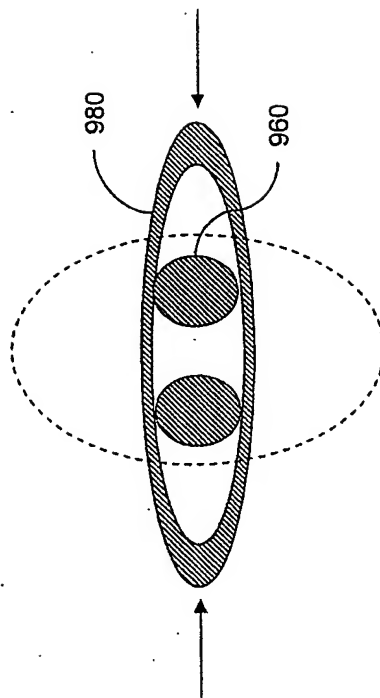


FIGURE 10E

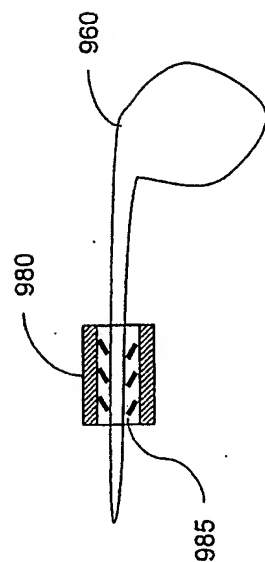


FIGURE 10D

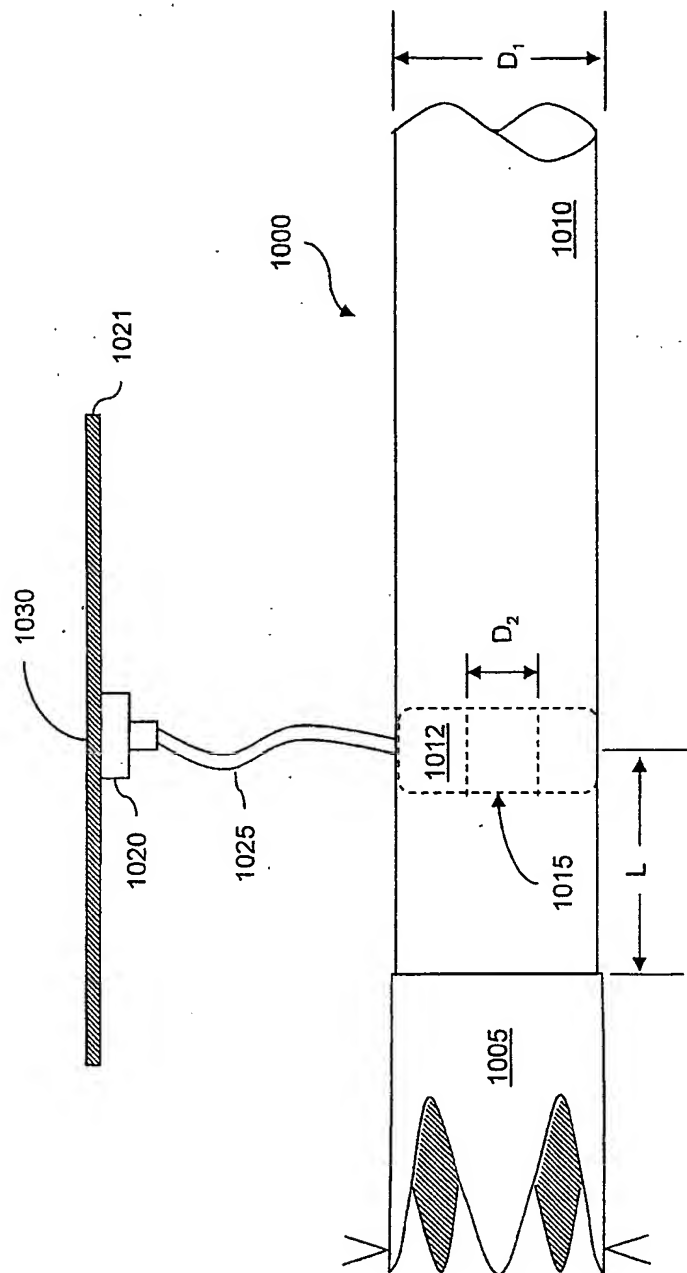


FIGURE 11A

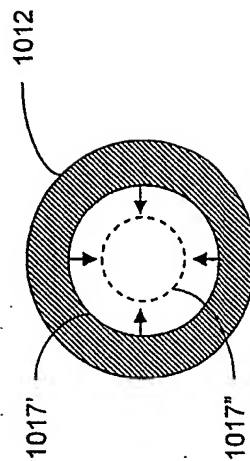


FIGURE 11B

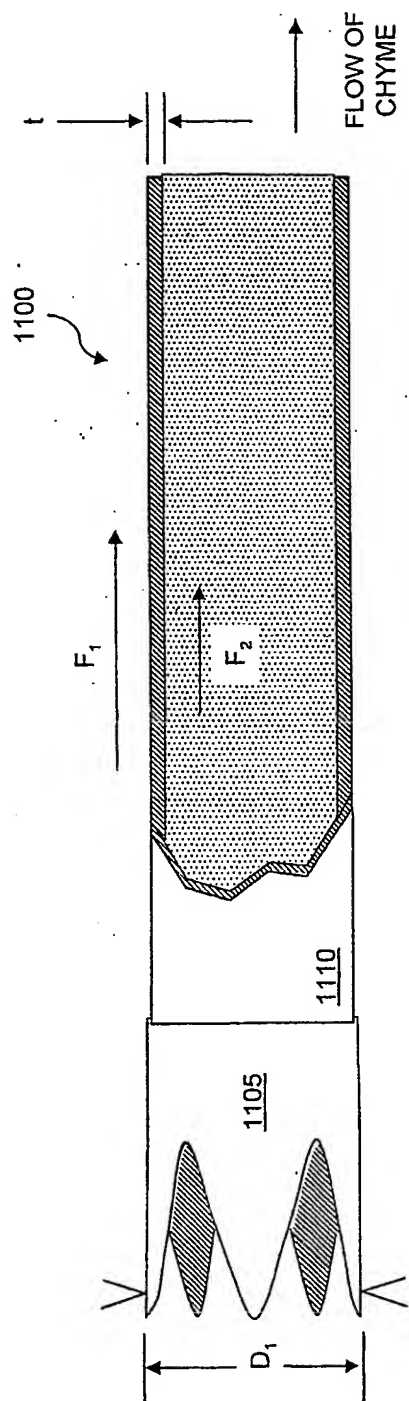


FIGURE 12

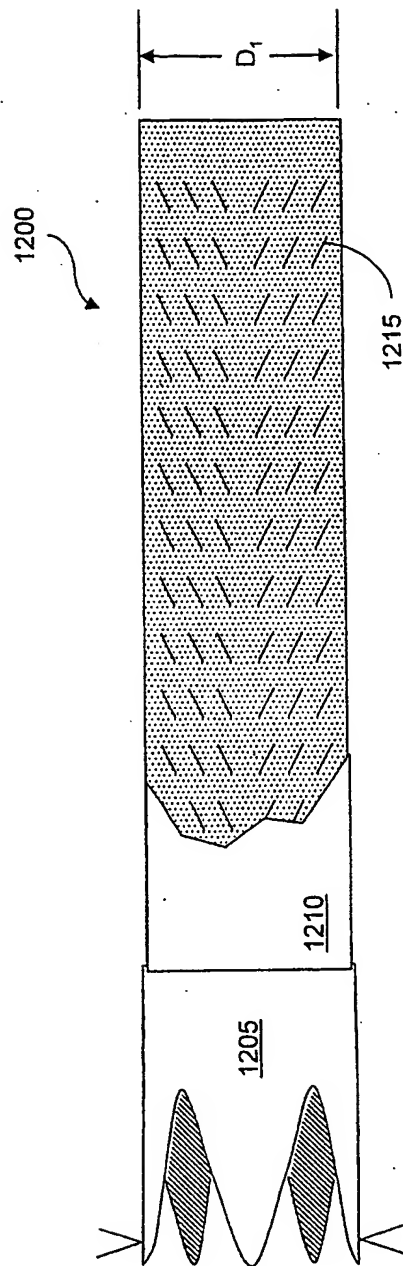


FIGURE 13

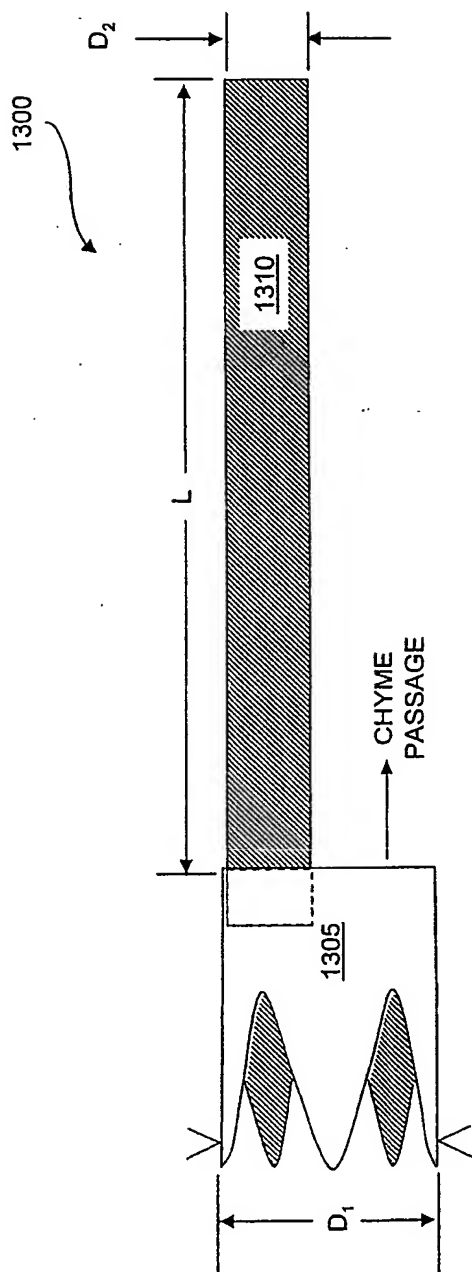


FIGURE 14A

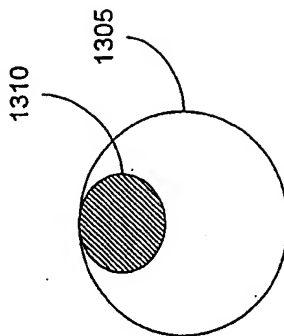


FIGURE 14B

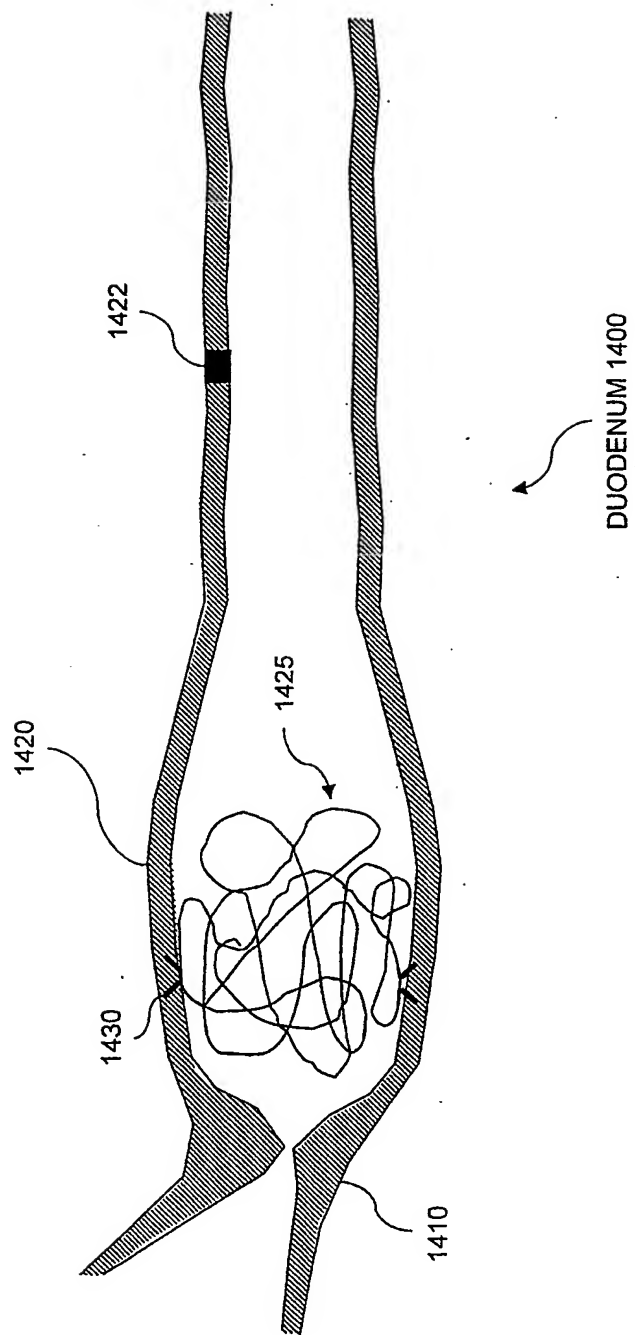


FIGURE 15

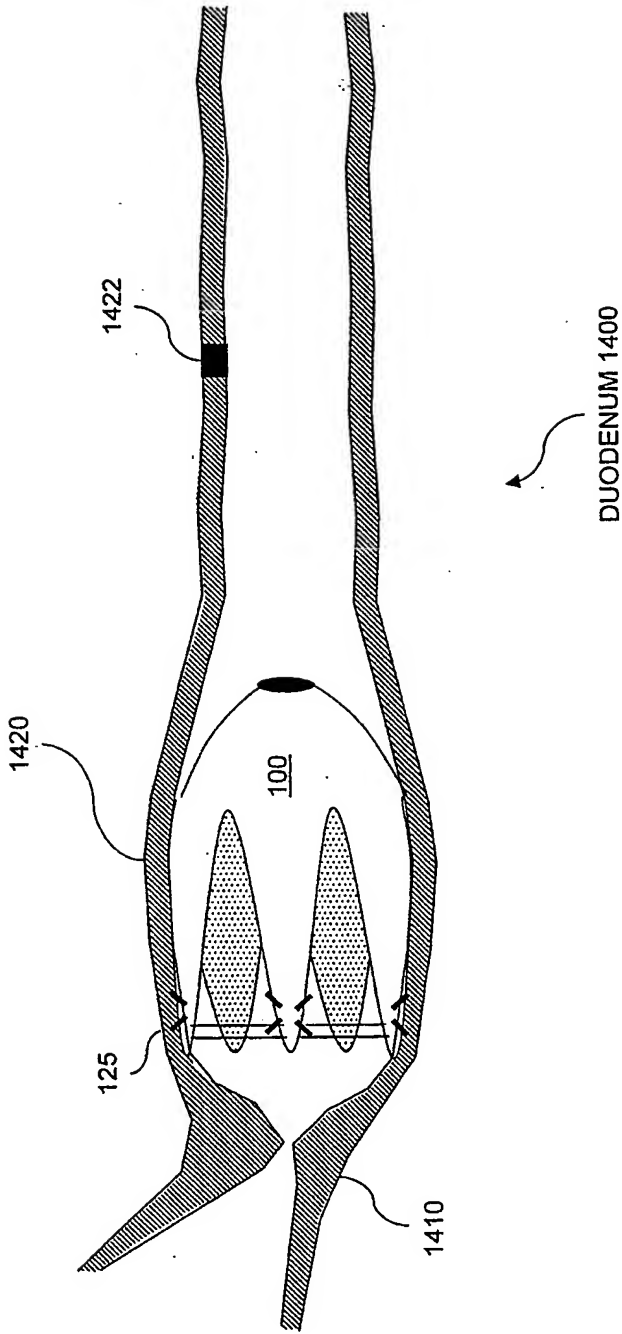


FIGURE 16A

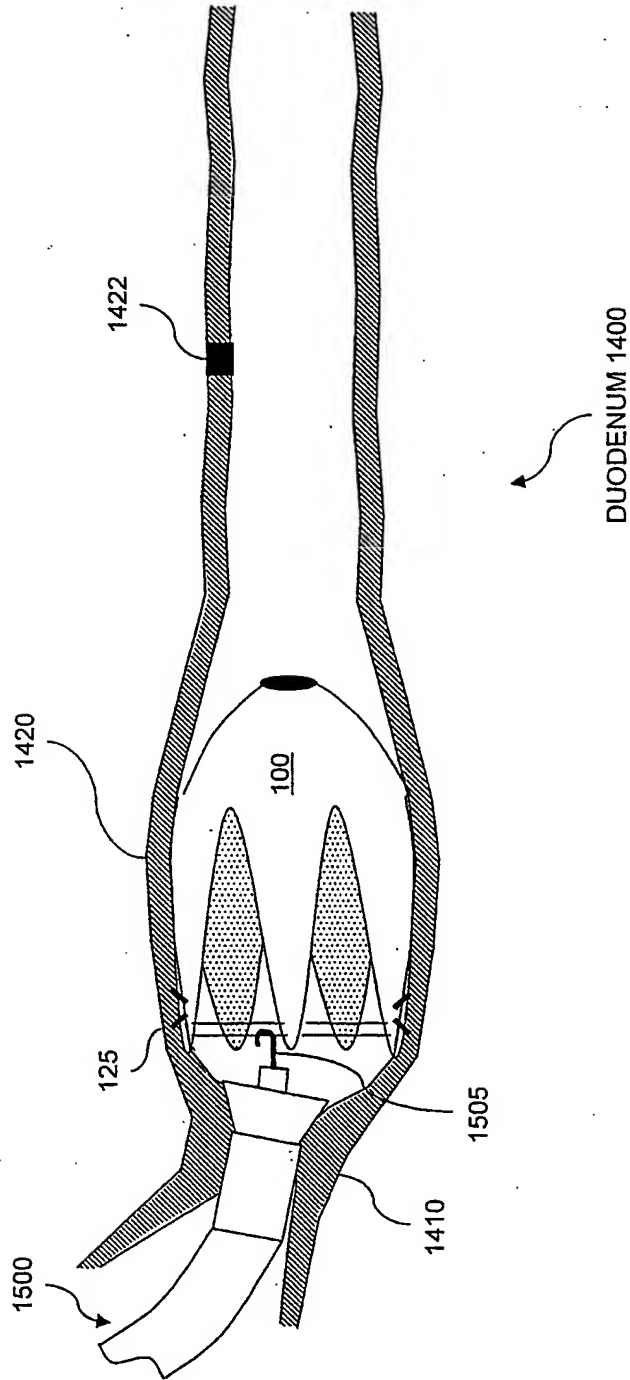


FIGURE 16B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/001842

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/040808 A1 (STACK RICHARD S ET AL) 27 February 2003 (2003-02-27) paragraph [0056] - paragraph [0057] paragraph [0061] - paragraph [0064] paragraph [0091] - paragraph [0093] paragraph [0098] - paragraph [0103] paragraph [0108]; figures 2,26,29-33	11-13, 16-20, 22-24
X	WO 2004/080336 A (SYNECOR, LLC) 23 September 2004 (2004-09-23) page 5, line 9 - line 26 sentence 7 - sentence 17 page 12, line 6 - line 14; figures 10,14a,14b	11-16, 19,20,24
A	US 2004/019388 A1 (STARKEBAUM WARREN L) 29 January 2004 (2004-01-29) abstract	11

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the International filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the International filing date but later than the priority date claimed

- *T* later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the International search

30 May 2006

Date of mailing of the International search report

13/06/2006

Name and mailing address of the ISA/

European Patent Office, P.B. 5918 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Arjona Lopez, G

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/001842

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-10
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2006/001842

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003040808 A1	27-02-2003	CN 1575155 A	02-02-2005
		EP 1420730 A2	26-05-2004
		JP 2005500127 T	06-01-2005
		WO 03017882 A2	06-03-2003
		US 2003199989 A1	23-10-2003
		US 2003199990 A1	23-10-2003
		US 2003199991 A1	23-10-2003
		US 2003040804 A1	27-02-2003
WO 2004080336 A	23-09-2004	EP 1603488 A2	14-12-2005
US 2004019388 A1	29-01-2004	NONE	